

**REMARKS**

A. Amendments to Claims.

Claims 1 and 12 are amended to clarify that the agent having ectoparasitocidal activity of the invention consists essentially of isopropyl myristate in a concentration between 35% and 70% w/w of the composition to be used according to the claims.

The 35% value replaces the 10% value in the claims prior to amendment. The amendment is supported by the Specification at, for example, paragraph [0020].

The claims now also require the composition used to be free of polysorbate 80. The amendment is supported in the Specification at, for example, paragraph [0029], line 4.

At least 82% of the treated ectoparasites are killed by the claimed treatment. The phrase “up to at least 82%” being objected to as potentially reading on killing one parasite, the term “up to” has been deleted from the claims.

No new subject matter is added by the amendments, whose entry and consideration is therefore respectfully requested.

B. Governing Law.

As set forth at MPEP 2143:

“The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. [citations omitted] “[I]t can be important to identify a reason that would have

prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." KSR, 550 U.S. at \_\_\_, 82 USPQ2d at 1396.

If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art."

In determining obviousness, the point is not whether the skilled person *could* have arrived at the invention by adapting or modifying the closest prior art, but whether the prior art provides a reasonable expectation that doing so would solve an objective technical problem or produce an improvement. In that respect, a prior art reference must be considered in its entirety, i.e., *including* those portions that lead away from the claimed invention (*W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984)).

C. Response to Rejections under Section 103(a), based on Singer U.S. Patent No. 4,147,800.

1. Response to rejection of claims 1-4 and 12-15 (Singer alone).

Applicant agrees that, as stated in the Action, Singer teaches that pure IPM is pediculocidal. However, it also shows that "it required not less than 70% of...isopropyl myristate to achieve a 100% mortality." (Col. 4, lines 30-32).

As shown in Figure 1, curve 2 of Singer, the pediculocidal efficacy of concentrations of IPM below the 70% level plummeted to less than 20%. At concentrations less than 40% IPM, the difference in efficacy compared to control was insignificant.

In view of Singer, one of ordinary skill in the art would have no reason to believe that concentrations of IPM below 70% could kill 4 times the number of ectoparasites he recorded after an exposure of only 10 minutes. The inventors have, however, discovered that Singer's data was misleading on this point.

In the present invention, a composition of IPM with a different carrier (not the polysorbate 80 used by Singer) produced at least 82% efficacy at IPM concentrations as low as 35% (see, Hepler Declaration, enclosed). Applicant need not explain the mechanism of action for its invention, nor why Singer's results were so poor. However, it is clear that polysorbate 80 is one of the chemicals whose use in the present invention is explicitly discouraged (Specification at paragraph [0029], line 4). It is therefore now excluded from the scope of the invention.

In short, Singer does not teach or suggest use of IPM as the sole ectoparasitocidal agent in an alcohol-free, insecticide-free, polysorbate 80-free composition to achieve at least 82% mortality in an ectoparasitocidal population exposed to the composition for 10 minutes. To the contrary, Singer teaches away from such a result.

Reconsideration and withdrawal of the rejection of claims 1-4 and 12-15 as amended is therefore respectfully requested.

2. Response to rejection of Claims 1-4, 12-15 and 32 (Singer in view of Reid).

Reid is added to Singer for its teaching of combing to remove killed lice and nits. However, Singer fails to render the claimed invention obvious for all the reasons stated above. Reid does not cure the noted deficiencies of Singer.

Reconsideration and withdrawal of the rejection of claims 1-4, 12-15 and 32 as amended is therefore respectfully requested.

D. Response to Rejections under Section 102(b), based on Singer U.S. Patent No. 4,147,800.

Claims 12-15 are rejected as being anticipated by Singer. Applicants respectfully disagree.

The claims are directed to use of a subtoxic (between 35% and 70%) concentration of IPM as the sole killing agent against ectoparasites. At such a concentration, at least 82% of ectoparasites are killed after a 10 minute exposure. The "up to" phrase noted in the claim as broadening the effect of Singer has been deleted.

Singer does not teach that 82% of ectoparasites can be killed using concentration of IPM between 35% and 70% after any length of time. To the contrary, as discussed in Section C-1 above, Singer teaches that such concentrations effectively failed to kill a statistically significant number of pests.

Reconsideration and withdrawal of the rejection of claims 12-15 as amended is therefore respectfully requested.

### **CONCLUSION**

All of the pending claims (1-4 and 12-15) are believed to be in condition for allowance. Favorable action thereon is therefore respectfully requested.

The Commissioner is hereby authorized to charge the total amount of \$635.00 to cover the Three Months Extension of Time fee to Deposit Account 07-1896. An extension of three months time for submission of this Response to Office Action is hereby requested.

In re Application of:  
William R. Campbell et al.  
Application No.: 10/692,979  
Filed: October 24, 2003  
Page 8

Attorney Docket No.: PIED1110-1

The Commissioner is also authorized to charge any other fees that may be due in connection with the filing of this paper, or credit any overpayment thereof, to Deposit Account No. 07-1896, referencing the above-identified docket number.

Respectfully submitted,

Date: December 20, 2011



Stacy L. Taylor

Registration No. 34,842

Telephone: (858) 677-1423

Facsimile: (858) 677-1465

DLA PIPER LLP (US)  
4365 Executive Drive, Suite 1100  
San Diego, California 92121-2133  
**USPTO Customer Number 28213**

Attachment: Rule 1.132 Declaration of Dr. Douglas Hepler